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HARMONIZED SYSTEM
REVIEW SUB-COMMITTEE

-
26th Session
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NR0316E1
(+ Annex I to III)

O. Eng.

Brussels, 31 July 2002.

POSSIBLE AMENDMENT OF HEADING 21.06 TO SPECIFICALLY
MENTION "FOOD SUPPLEMENTS"
(Item III.A.3 on Agenda)

Reference documents :

NR0187E1 (RSC/24)
NR0205E2, Annex D/5 (RSC/24 – Report)
NR0225E1 (RSC/25)
NR0257E1 (RSC/25)

NR0263E1 (RSC/25)
NR0265E3, Annex C/15 (RSC/25 – Report)
02NL0541 – GI/FI of 13 June 2002
NR0273E1 (RSC/26)

I. BACKGROUND

1. Following the invitation of the Chairman of the Review Sub-Committee, as mentioned in paragraph 7 of Doc. NR0273E1, the Secretariat sent a letter to several administrations asking them to provide information on the use of definitions of "food supplements" in their administrations.
2. To date the Secretariat has received comments in response to its letter from the Administrations of Canada, the Russian Federation and South Africa, which are set out in Annexes I to III to this document, respectively.

II. CONCLUSION

3. The Sub-Committee is requested to take the comments set out in Annexes I to III to this document into account, when examining this agenda item.

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Note : Shaded parts will be removed when documents are placed on the WCO documentation database available to the public.

File No. 2522

NR0273E1

COMMENTS FROM CANADA

"Your letter indicates that the proposals introduced at the 25th Session the Review Sub-Committee in an effort to provide a clearer definition of "food supplements" have been left open for the next RSC meeting. It also invites individual administrations to provide definitions used in their national legislation with regard to "food supplements" for possible inclusion in a new working document.

In **Canada**, the relevant national legislation is the Food and Drugs Act (FDA) administered by **Health Canada**, which is the federal department "responsible for helping the people of **Canada** maintain and improve their health". The FDA does not include a definition of a "food supplement". However, it does define the following related term :

Nutritional supplement : "means a food sole or represented as a supplement to a diet that may be inadequate in energy and essential nutrients".

We believe that the terms "food supplement" and "nutritional supplement" could probably be considered synonymous terms. The Merriam-Webster online dictionary refers to food as "something that nourishes, sustains, or supplies" and refers to nutrition as "the act or process of nourishing or being nourished".

In addition, and while this goes beyond the scope of your request, we have included the following definitions which relate to developing trends in the food technology industry. Our purpose in including these is merely to make you aware of types of products which may present classification difficulties in the future because there may be difficulty determining whether they are food preparations or medicaments. These two working definitions may also assist in understanding the term "supplement" as used by **Canadian** health authorities :

Functional food : "is similar in appearance to, or may be a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions".

Nutraceutical : "a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease".

The Secretariat may be interested in knowing that **Health Canada** has recently established the Office of **Natural Health Products (ONHP)**. The **ONHP** has proposed that products which are comprised of particular medicinal ingredients, including vitamins, minerals, amino acids and digestive enzymes, be considered natural health products and has proposed the following definition of a "natural health product".

Natural Health Products : "substances or combinations of substances consisting of molecules and elements found in nature, and homeopathic preparations, sold in dosage form for the purpose of maintaining or improving health and treating or preventing diseases/conditions".

The specific requirements of **Health Canada** with respect to "dietary vitamin supplements" and "mineral supplements" may be of interest. These requirements are set out in monographs and reflect the related legislation in the Food and Drugs Act. A vitamin or a

mineral supplement in dosage form and containing a designated minimum amount of the specific vitamin or mineral is considered a drug according to the FDA. A vitamin or a mineral supplement that contains more than a designated amount of the specific vitamin or mineral must be presented with a label specifying "for therapeutic use only".

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COMMENTS FROM THE RUSSIAN FEDERATION

"As the description of "food supplements" in the Explanatory Notes applies to heading 21.06 (Item 16, page 183) and also heading 30.04 (the last paragraph, page 572), and the term "food supplements" is used in Note 1 (a) to Chapter 30, we believe that the question of "food supplements" should be considered taking the present definitions into consideration.

The definition on page 183 of the Explanatory Notes describes food supplements, based on natural biological active components – plants extracts, fruit concentrate, honey, fructose, etc. with added vitamins and minerals. These supplements are used for health strengthening and health improvement.

The definition on page 572 of the Explanatory Notes describes "food supplements", containing vitamins and minerals for health strengthening and health improvement.

The both kinds of supplements, as a rule, are supplied in the form of tablets, capsules or powder. They are sold in drug-stores without prescription and are produced as balanced supplement to food aiming health strengthening and health improvement.

Thus the above supplements, influencing human-being organism biologic actively have an important function of stimulation and regulation of physiological processes in the organism and of improving human-being organism resistibility.

Daily consumption of vitamins and minerals, necessary for human-being organism let someone to prevent any diseases, caused by deficiency of them. Besides, vitamins and minerals are used for the treatment for diseases, caused by a deficiency of vitamins and minerals, also as roborant for other various diseases including infectious ones.

As supplements, based on plant extracts, fruit concentrates, honey, etc., also on vitamins and minerals mixtures, are final products and are intended for balanced supplements to food we suggest that definition "food supplements" should be used for such kind of products.

We believe that the definition "food supplements" describes the essence of the subject more exactly. Besides the definition "food supplements" enables us to distinguish the given products from the other group of supplements sometimes called "food supplements" especially brought in foodstuffs during their production to give definite characteristics to foodstuffs and (or) to maintain foodstuff quality.

Taking into consideration the fact, that the above goods become more significant in foreign trade and that as a rule of non-tariff measures such as national health authorities release and registration are taken in respect of these goods, we believe that it is necessary to consider the question of separation of "food supplements" into separate subheading to heading 21.06.

In connection with the above we propose the following alterations and amendments to the HS and Explanatory Notes :

Heading 21.06

21.06 Food preparations not elsewhere specified or included.
2106.10 - Protein concentrates and textured protein substances

[**2106.20** "Food supplements" for balanced supplement to food]
2106.90 - others

A new Note to subheading 2106.20

[In subheading 2106.20 the term "food supplements" means preparations intended for balanced supplement to food and used for the prevention or treatment of diseases or ailments, based on :

1. plant extracts, fruit concentrates, honey, etc. with added vitamins or minerals or vitamin and minerals mixtures;
2. vitamins or other compounds of heading 29.36 and minerals; or
3. minerals or mixtures thereof.]

Explanatory Notes to Chapter 21

A new wording of Item 16 of the Explanatory Note to heading 21.06 with regard to Secretariat Doc. NR0225E1 :

[16. Preparations, consisting of plant extracts, fruit concentrates, honey, fructose, etc. with added vitamins and minerals, amino acids, important fat acids and etc. intended for using as supplements to food. The given preparations are sold in measured out in doses form (capsules, powders, ampoules or liquid, etc.) in packaging with using indication where it is marked that they enable us to maintain and strengthen good health.

Similar preparations, which however are intended for treatment for diseases or ailments are excluded from this definition (heading 30.03 or 30.04).

A new Item of the Explanatory Note to heading 21.06 :

[17. Preparations consisting of vitamins or other compounds of heading 29.36 and minerals, or minerals or minerals mixtures. The preparations contain excipient, sweetening agent, agglomerating agent, support etc. and are usually produced in form of tablets, capsules or in other measured forms. There is usually indication on packaging, saying that these preparations promote health maintaining and strengthening also are used in therapeutic and prophylactic purposes as far as some diseases or indisposition (such as diseases caused by deficiency of vitamins or minerals) are concerned.

However, the preparations based on pharmaceutical substances, specific with respect to definite diseases connected with added vitamins, minerals or mixtures of these vitamins and minerals, intended for therapeutic and prophylactic purposes are not included (heading 30.03 or 30.04).

Note 1 (a) to Chapter 30 :

- (a) Foods or beverages (such as dietetic, diabetic or fortified foods, **[food supplements]** tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (Section IV)."

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COMMENTS FROM SOUTH AFRICA

"**Food supplement**" has the same meaning as nutritional supplement.

"**Nutritional supplement**" means products containing any natural occurring molecules and molecules synthesised by chemical or biological means or botanical extracts, derivatives, concentrates, enzymes, co-enzymes, co-factors, naturally occurring hormones and precursors, animal source substances or metabolites intended to be consumed for its nutritional value in the maintenance and improvement of human health. A nutritional supplement must be in a dosage form such as capsules, tablets, liquids or powders; it includes but is not limited to vitamins, minerals, co-factors, essential fatty acids, amino acids, enzymes and co-enzymes, animal or botanical extracts and derivatives, probiotics and non-nutrient dietary phytoprotectants in a dosage form such as capsules, tablets, liquids or powders."
